

ATTACHENT B

for 16 to 20 days. Each capsule contained 1000 mg of d-limonene having a purity of from 98.5% to 99.3%.

Table 1 shows the pre-treatment severity and frequency ratings for the participants in each of the treatment regimens. Table 2 shows the percentage of participants experiencing complete relief or a severity rating=1-2 at different days through the treatment period for the different treatment regimens (i.e. every day and every other day). FIG. 1 is a graph illustrating the data shown in Table 2. FIG. 3 is a graph illustrating the percentage of all the participants (i.e. those undergoing the every other day regimen and every day regimen) having a severity rating of 1.

TABLE 1

Pre-Study Symptom Ratings				
	Avg. Severity	Range (Severity)	Ave. Freq.	Range (Freq.)
Every day regimen	8	5-10	8.1	6-10
Every other day regimen	7.9	3-10	7.4	2-9
Overall	7.8	3-10	7.3	2-10

TABLE 2

Post Treatment Regimen Symptom Ratings					
	Day 2	Day 4	Day 7	Day 9	Day 14
% of all participants with symptom rating = 1-2	32%	32%	63%	74%	89%
% of participants (every day regimen) with symptom rating = 1-2	14%	29%	57%	71%	86%
% of participants (every other day regimen) with symptom rating = 1-2	42%	42%	67%	75%	92%

When comparing the results of all of the participants, about 20% achieved complete relief of symptoms (rating of 1) as early as day 2 of their regimen. The percentage of participants achieving complete relief of symptoms gradually increased over time, with 79% of the participants achieving complete relief by day 14. About 32% of the total participants achieved significant relief (rating 1-2) by day 2 with an increase to 89% of participants experiencing complete symptom relief or severity rating of 1-2 by day 14.

In comparing the two treatment regimens (i.e. every other day vs. every day), it was discovered that those taking one gram of d-limonene every other day experienced earlier symptom relief with a higher percentage of participants (about 92%) experiencing complete relief by day 14.

Table 3 and FIG. 3 compare the percentage of total participants suffering from severe heartburn or GERD vs. those participants suffering from mild/moderate heartburn who experienced "severity" and "frequency" symptom ratings of 1-2. Results showed that those with mild/moderate heartburn experienced symptom relief sooner than those suffering from more severe heartburn/GERD; however, the final outcome by day 14 was about the same.

TABLE 3

Pre-Study Symptoms	Day 4	Day 7	Day 9	Day 11	Day 15
Severe heartburn/GERD group	0%	38%	38%	72%	88%
Mild/moderate heartburn group	55%	82%	82%	91%	91%

EXAMPLE 2

A preliminary double-blind placebo study was conducted on 13 participants suffering from mild/moderate heartburn to severe heartburn/GERD. Seven participants were administered the product and six were administered a placebo. In the "limonene" group (i.e. 1 capsule containing 1 gram of 98% d-limonene), two participants were administered 1 capsule every day for five days followed by 1 capsule every other day for five days. The remaining "limonene" group participants were administered 1 capsule every other day for 20 days. In the "placebo" group, three participants were administered 1 placebo capsule (i.e. gelatin capsule containing soybean oil) daily for five days, followed by 1 capsule every other day for 5 days. Two participants were administered 1 placebo capsule every other day for 20 days while one participant having severe heartburn was administered 1 placebo capsule twice a day for 5 days, followed by 1 capsule every day for 5 days, followed by 1 capsule as needed. As shown in Table 4 (and FIG. 4), a significant difference in results was obtained between the two groups (n=14).

TABLE 4

Product vs. Placebo				
Compound	Day 4	Day 7	Day 9	Day 14
d-limonene product	29%	29%	71%	86%
Placebo	0%	14%	29%	29%

EXAMPLE 3

An atmospheric distillation unit was charged with 100 milliliters of 96-96.5% Food Grade limonene. The distillation unit was operated with a reflux ratio of 1:1. The desired limonene distillate was removed in a range of from about 340° F. to 390° F. and was of a purity of about 98%.

I claim:

1. A method for the treatment of gastrointestinal disorders, said method comprising orally administering to a person in need of such treatment a therapeutically effective amount of limonene.

2. The method of claim 1, wherein said gastrointestinal disorder is selected from the group consisting of heartburn, gastro esophageal reflux disorder, and gastric indigestion.

3. The method of claim 2, wherein said amount of limonene is from about 500 mg to about 1000 mg administered every day to said person for at least two days.

4. The method of claim 3, wherein said amount is 1000 mg.

5. The method of claim 2, wherein said amount of limonene is from about 500 mg to about 1000 mg administered every other day to said person for at least four days.

6. The method of claim 5, wherein said amount is 1000 mg.